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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,494	07/25/2001	Robert Thomas Hudak	AC-00127.P.1	6752

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

11

Office Action Summary

Application No.

09/915,494

Applicant(s)

HUDAK, ROBERT THOMAS

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24 and 28-73 is/are pending in the application.
- 4a) Of the above claim(s) 61-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24 and 28-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/24/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed 02/22/05 is acknowledged and has been entered.

Election/Restrictions

1. Newly submitted claims 61-73 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 61-73 require a valve transversely interposed between said chamber and said reservoir and claim 1 does not require this limitation. Further, Claim 1 requires said valve having at least one valve O-ring and being leak resistant between the chamber and the reservoir from about 0 PSI to about 50 PSI of internal pressure and claim 61 does not require this limitation. Therefore the inventions are independent and distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61-73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 11, 13-17, 19-22, 24, 28, 29, 31, 33-40, 44-47, 49 and 51-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Guirguis et al (US 6,277,646).

Guirguis et al disclose a device and method for determining an analyte of interest. Guirguis et al disclose a collection chamber and an isolation chamber for receiving a specimen. Guirguis et al disclose a fluid path for receiving a portion of the specimen from the isolating chamber (col. 11, lines 40-64, Figures 9-11). Guirguis et al disclose a fluid releasing element (valve) provided with a penetrating member which, when pressure is applied from the lid penetrates or breaks the frangible bottom wall enabling the fluid sample to flow to a fluid flow path (reservoir) (Figures 9-11). Guirguis et al disclose the device comprises a test chamber in fluid communication with the fluid flow path. Guirguis et al disclose test chamber may comprise a test device such as a test strip such as antigen/antibody test strips (col 6). Guirguis et al disclose the device contains a lid which forms a fluid tight seal (col 10). Guirguis et al disclose that the fluid releasing element (valve) may comprise an o-ring (col 13, lines 50-52).

With respect to the recitation "wherein said valve is inoperable after a first actuation" as recited in the instant claims. Guirguis et al disclose that the fluid releasing element is engaged by pressure applied to the fluid releasing element by the lid when the lid engages with the container (col 11). In the embodiment disclosed by Guirguis et al the lid is not attached to the fluid releasing element. Therefore the pressure of the lid forces the fluid releasing element (valve) into the isolating chamber and forms a tight seal. Therefore, when the lid is removed the fluid releasing element stays in place and

thus is only operable once. Therefore, Guirguis et al reads on the instantly recited claims.

With respect to the O-ring being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure as recited in the instant claims. Guirguis et al teaches that the fluid releasing element can comprise an O-ring which provides for a fluid tight seal (col 13, lines 43-64). With respect to the 0 PSI to about 50 PSI as instantly recited. Since Guirguis et al disclose the same structural features as instantly claimed the valve would be capable of being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure.

With respect to amended claim 24 as recited in the instant claims. Guirguis et al teaches that the fluid releasing element (valve) can comprise an O-ring for forming a fluid tight seal (first seal) (col 13, lines 43-61) and also teaches that the fluid releasing element can also comprise a solid portion 174 of the fluid releasing element sized so that a fluid tight seal is formed (second seal). Therefore, Guirguis et al discloses that the fluid releasing element (valve) can comprise first and second seals.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 6-8, 18, 24 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guirguis et al in view of Alley (US 2002/00446614).

See above for teachings of Guirguis et al.

Guirguis et al differ from the instant invention in failing to teach the seal comprises at least one O-ring.

Alley discloses a seal comprising an O-ring. Alley discloses that the use of this O-ring provides a means of securing the seal to the container. Furthermore, the use of O-rings in a seal is well known in the art.

It would have been obvious to one of ordinary skill in the art to incorporate an O-ring as taught by Alley into the device of Guirguis et al because Alley shows that the use of this O-ring provides a means of securing the seal to the container.

With respect to the specimen volume as recited in the instant claims, the optimum specimen volume can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior

art, it is not inventive to discover the optimum of workable ranges by routine experimentation.” Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation .” Id. At 458,105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

7. Claims 9, 30, 32, 43, 48 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guirguis et al in view of Ehrenkranz (US 4,769,215).

See above for teachings of Guirguis et al.

Guirguis et al differ from the instant invention in failing to teach the chamber comprises a temperature-sensing device.

Ehrenkranz discloses a urine collection apparatus, which comprises a thermometer within the device. Ehrenkranz discloses that the use of this thermometer provides a means for determining the freshness of the urine and also provides an alternative for physical examination (col. 5, lines 19-37 and abstract).

It would have been obvious to one of ordinary skill in the art to incorporate the thermometer as taught by Ehrenkranz into the device of Guirguis et al because Ehrenkranz shows that the use of this thermometer provides a means for determining the freshness of urine and also provides an alternative for physical examination.

With respect to the recitation “wherein said reservoir is removable from said chamber” as recited in the instant claims. Guirguis et al disclose the claimed invention except for

teaching the reservoir is removable from the chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the chamber and reservoir as separate parts, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

With respect to claim 24 as recited in the instant claims. Guirguis et al teaches that the fluid releasing element can comprise an O-ring for forming a fluid tight seal (col 13, lines 43-61) and also teaches that the fluid releasing element can comprise a stopper (seal) (col 11, lines 41-64). Therefore, Guirguis et al discloses that the fluid releasing element (valve) can comprise first and second seals.

8. Claims 10, 12, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guirguis et al. in view of Kantner (US 4,211,749).

See above for teachings of Guirguis et al.

Guirguis et al differ from the instant invention in failing to teach the chamber comprises a label on which to record data pertaining to the specimen. Guirguis et al also fails to teach the chamber is tapered.

Kantner disclose a urine container, which comprises an informative label containing important information relative to the patient in a manner ensuring that the label is not lost. Furthermore, it is well known in the art to place a label on a container to record patient information on the container. Kantner et al also disclose the container is tapered. Kantner disclose that this provides nesting of successive containers on top of one another. Kantner

also teach that the container is made of plastic which allows for a successful and cheap material (col. 15, lines 1-14).

It would have been obvious to incorporate a label such as taught by Kantner et al in the device of Guirguis et al because Kantner shows that the use of such a label provides for important information relative to the patient in a manner ensuring that the label is not lost. It also would have been obvious to one of ordinary skill in the art to taper the device of Guirguis et al such as taught by Kantner because Kantner discloses that this provides nesting of successive containers on top of one another.

9. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guirguis et al in view of LaBorde (US 2004/0053423).

See above for teachings of Guirguis et al.

Guirguis et al differ from the instant invention in failing to teach the test device comprises a wick.

LaBorde teaches a test strip comprising a wicking pad. LaBorde teaches that this wicking pad enhances the capillary action which drives flow from the introduction at one end of the membrane through the entire length of the membrane (paragraph 0011).

It would have been obvious to one of ordinary skill in the art to incorporate a wicking pad as taught by LaBorde into the device and method of Guirguis et al because Guirguis et al teaches the use of any conventional test strip and further because LaBorde teaches the use of the wicking pad enhances the capillary action which drives flow from the introduction at one end of the membrane through the entire length of the membrane and therefore one of ordinary

skill in the art would have a reasonable expectation of success incorporating a wicking pad such as taught by LaBorde into the device and method of Guirguis et al.

10. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guirguis et al in view of Pampinella (US 2002/0023482).

See above for teachings of Guirguis et al.

Guirguis et al differs from the instant invention in failing to teach the valve comprises a handle for actuating the valve, wherein the handle functionally disengages from the valve after the valve is actuated and wherein the valve cannot be actuated with the handle functionally disengaged therefrom.

Pampinella teaches a valve handle which is detachably connected to the valve (page 1, paragraph 0034). Pampinella teaches that the use of this valve facilitates the opening and closing of the valve.

It would have been obvious to one of ordinary skill in the art to incorporate a handle such as taught by Pampinella with the valve of Guirguis et al because Pampinella teaches that the use of this valve facilitates the opening and closing of a valve.

With respect to the recitation " wherein the valve cannot be actuated with the handle functionally disengaged therefrom" as recited in the instant claims. One of ordinary skill would recognize that when the handle of Pampinella is detached the valve could not be engaged.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 22-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 10/211,199. Although the conflicting claims are not identical, they are not patentably distinct from each other because one skilled in the art would recognize that the narrow claims of the device concerning the valve in application 10/211,199 would encompass the more broad claims of the device in application 09/915,494 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

12. Applicant's arguments filed 02/22/05 have been fully considered but they are not persuasive. .

102 Rejection Arguments:

Applicant argues that the presented claims are not anticipated by Guirguis because Guirguis does not disclose or suggest " a valve having at least one valve O-ring functionally interposed between said chamber and said reservoir, said valve being

leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure". This is not found persuasive because Guirguis et al disclose that the fluid releasing element (valve) may comprise an o-ring (col 13, lines 50-52). Further, With respect to the O-ring being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure as recited in the instant claims. Guirguis et al teaches that the fluid releasing element can comprise an O-ring which provides for a fluid tight seal (col 13, lines 43-64). With respect to the 0 PSI to about 50 PSI as instantly recited. Since Guirguis et al disclose the same structural features as instantly claimed the valve would be capable of being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure. Thus, Guirguis et al reads on the instantly recite claims.

Applicant argues that Guirguis teaches either a "lance" valve with a penetrating member that breaks through a frangible bottom wall, or alternatively a stopper that plugs a hold (which the Examiner incorrectly refers to as a valve). This is not found persuasive because it appears Applicant has misinterpreted the stopper to be the plug Examiner was referring to. The plug 140 which was referred to as a valve was disclosed by Guirguis et al also as a fluid releasing element (col 11, lines 40-64, Figures 9-11). Therefore, the term plug and fluid releasing element is equivalent. However, in order to clarify that the plug is not the stopper, Examiner has replaced the term plug with fluid releasing element. Applicant further argues that the valves of Guirguis et al does not prevent leakage of used sample back through the valve and into the chamber. This is not found persuasive because Guirguis et al disclose the same structures as

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instantly claimed and therefore would be capable of preventing leakage of used sample back through the valve and into the chamber. Further, as stated above Guirguis et al disclose the valve can comprise an O-ring which provides a fluid tight seal.

103 Rejection Arguments:

Applicant argues that amended claim 1 recites “ a valve having at least one valve O-ring functionally interposed between said chamber and said reservoir, said valve being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure” and that none of the cited references, neither alone nor in combination with one another, teach or suggest a specimen collection device having leak resistant valve having an O-ring that is leak resistant at about 0 PSI to about 50 PSI. This is not found persuasive because of reasons stated above. Applicant further argues that the types of valves taught in the various references cannot maintain leak resistance at increased pressures. This is not found persuasive because Applicant has not recited any structural features which are different that that of Guirguis et al and therefore since Guirguis et al teach the same structural limitations as the instantly recited claims the device of Guirguis et al is capable of maintaining leak resistance at increased pressures. Further, with respect to Applicant’s statement that “the types of valves taught in various references cannot maintain leak resistance at increased pressures”, arguments of counsel cannot take the place of evidence . *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). (see MPEP 716.01(c).)

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
March 4, 2005



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SUPERVISORY PATENT EXAMINER
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03/04/05